AUG 1 1 2005

SUMMARY OF SAFETY AND EFFECTIVENESS
Valleylab ForceTriad™ Electrosurgical Generator

K051644

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1. Submitter Information

Valleylab, a Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Herbert Vinson
Telephone: 303-530-6469

Date summary prepared: June 17, 2005

2. Name of Device

Trade or Proprietary Name:
Valleylab ForceTriad™ Electrosurgical Generator

Common Name: Electrosurgical Generator

Classification Name:

- Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery
- Class II, 21 CFR 884.4120, Gynecologic Electrocautery and Accessories

3. Predicate Devices

The ForceTriad™ Electrosurgical Generator is substantially equivalent in function and intended use to the following legally marketed devices: Valleylab Force FX™ Electrosurgical Generator (K944602) and the Valleylab LigaSure™ Vessel Sealing System (K981916). The ForceTriad™ generator and the Force FX™ generator both have monopolar and bipolar electrosurgical outputs and are intended for all types of surgical procedures where electrosurgery is desired. Both have a selection of CUT and COAG monopolar outputs, and can be used with conventional electrosurgical devices. The ForceTriad™ generator has an additional monopolar output, Hemostasis with Division, that allows the surgeon to maintain controlled hemostasis while dividing tissue. The HWD output has power output and maximum voltage output in the same range as the other monopolar outputs. It is available when using the Valleylab G3000 electrosurgical device.

The ForceTriad™ generator and the LigaSure™ vessel sealing generator both have outputs for LigaSure™ vessel sealing devices. The output power and voltage of the generators are equivalent.

4. Device Description

The ForceTriad™ generator is a full-featured electrosurgical generator with monopolar, bipolar, and Valleylab LigaSure™ vessel sealing outputs. The generator

is an electrically isolated, microcontroller-based device, incorporating closed-loop control for all output modes implemented in the microcontroller firmware. The generator incorporates Instant Response™ technology to constantly measure the electrical impedance of the tissue and instantaneously adjust the generator output to maintain the desired power.

Available output modes include:

Monopolar

- Cut : clean, precise cut in tissue, with little or no hemostasis
- Blend: blended waveform for slower cutting and additional hemostasis
- Hemostasis with division (HWD): optimized division of tissue with controlled hemostasis and minimal thermal damage to adjacent tissue
- Fulgurate: tissue coagulation by sparking
- Spray: fulguration with shallower penetration over larger tissue areas

Bipolar

- Low: precise, controlled desiccation of tissue
- Standard: general bipolar desiccation with consistent tissue effect
- Macro: rapid coagulation and bipolar cutting in a wide range of tissues

LigaSure™ vessel sealing

- Seals vessels (arteries, veins, lymph) 7mm and less, and tissue bundles.

The monopolar Cut, Blend, Fulgurate, and Spray output modes are designed for use with conventional handswitching or footswitching electrosurgical devices. The three bipolar output modes are designed for use with conventional handswitching or footswitching electrosurgical bipolar forceps. When using conventional electrosurgical devices, the user selects the mode and desired power using a touch screen display on the generator.

All monopolar output modes, including HWD, are also designed for use with Valleylab electrosurgical devices with surgeon power control. The surgeon power control devices utilize Valleylab Smart™ connector technology that allows the generator to identify the type of device in use. After recognizing the device type, the generator establishes five power zones for each output mode. The generator defaults to power zone 3, but the surgeon may select an alternate power zone using the touch screen. From the sterile field, the surgeon then uses the slider switch on the device to select the desired power setting within the selected power zone. The surgeon activates the desired output mode (CUT, HWD, COAG) using the buttons on the device. The surgeon also has the option of using the touch screen controls to select power levels outside the pre-established power zones to accommodate unusual surgical situations.

Monopolar electrosurgery requires the use of a patient return electrode ("return pad" or "grounding pad") with Valleylab REM™ return electrode monitoring. The REM™ system continuously verifies contact between the patient and pad to prevent pad-site burns. (Valleylab REM™ electrodes were initially cleared for marketing on K822572, and have been used on all Valleylab electrosurgical generators since that

time.) Bipolar devices and LigaSure™ vessel sealing devices do not require patient return electrodes.

The ForceTriad™ vessel sealing mode is designed for use with LigaSure™ vessel sealing devices. The LigaSure™ devices utilize Smart™ connector technology to allow the generator to recognize the device in use and set the generator output accordingly. (Refer to K981916, LigaSure™ Vessel Sealing System.)

5. **Intended Use**

The ForceTriad™ generator is a full-featured electrosurgical generator intended for open and laparoscopic surgical procedures where the surgeon requires electrosurgical cutting, coagulation, or vessel sealing (tissue fusion) in general, urologic, thoracic, plastic and reconstructive, arthroscopic, gynecologic and similar surgery. The ForceTriad™ generator is intended for use in the operating room, surgery center, or clinic. The generator has both monopolar and bipolar outputs that accommodate standard electrosurgical devices and Valleylab electrosurgical devices with surgeon power control. The ForceTriad™ generator also incorporates the functionality of the Valleylab LigaSure™ vessel sealing system, and accepts Valleylab LigaSure™ devices.

Valleylab makes the following recommendations with regard to the use of the ForceTriad™ electrosurgical generator.

- Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical or tissue fusion appliances is planned in patients with cardiac pacemakers.

- If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical or tissue fusion procedure. Electrosurgery or tissue fusion may cause multiple activations of ICDs.

Valleylab recommends against the use of laparoscopic surgery on pregnant patients.

LigaSure™ tissue fusion has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

6. **Summary of Technological Characteristics**

The ForceTriad™ Electrosurgical Generator has the same basic technological characteristics as the predicate devices noted above.

7. Performance Data

Performance testing was performed to ensure that the ForceTriad™ Electrosurgical Generator functions as intended, and meets design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2005

Valleylab
Division of Tyco Healthcare Group LP
Mr. Herbert Vinson
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301

Re: K051644
Trade/Device Name: Force Triad™ Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 17, 2005
Received: June 20, 2005

Dear Mr. Vinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Brechner
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051644

Device Name: ForceTriad™ Electrosurgical Generator

Indications For Use:

The indications for use include general (including urologic, thoracic, plastic and reconstructive, arthroscopic), laparoscopic, and gynecologic procedures where electrosurgical cutting and coagulation of tissue, and sealing (fusion) of vessels and tissue bundles is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholesystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. Vessels (arteries, veins, lymph) 7mm and smaller in diameter, and bundles as large as will fit in the jaws of the devices can be sealed with the LigaSure™ vessel sealing (tissue fusion) output.

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Barbara Buchwald for

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K051644